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| APPLICATION NO.       | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.   | CONFIRMATION NO. |
|-----------------------|-------------|----------------------|-----------------------|------------------|
| 10/507,057            | 09/07/2004  | Pierre Roy           | 079777-0564 (EGS-005) | 8466             |
| 48329                 | 7590        | 04/14/2009           | EXAMINER              |                  |
| FOLEY & LARDNER LLP   |             |                      | KOHARSKI, CHRISTOPHER |                  |
| 111 HUNTINGTON AVENUE |             |                      |                       |                  |
| 26TH FLOOR            |             |                      | ART UNIT              | PAPER NUMBER     |
| BOSTON, MA 02199-7610 |             |                      | 3763                  |                  |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

|                              |                         |                     |
|------------------------------|-------------------------|---------------------|
| <b>Office Action Summary</b> | <b>Application No.</b>  | <b>Applicant(s)</b> |
|                              | 10/507,057              | ROY ET AL.          |
|                              | <b>Examiner</b>         | <b>Art Unit</b>     |
|                              | CHRISTOPHER D. KOHARSKI | 3763                |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 12 January 2009.  
 2a) This action is **FINAL**.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-27 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-27 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____.   | 6) <input type="checkbox"/> Other: _____ .                        |

## **DETAILED ACTION**

### ***Acknowledgements***

The Examiner acknowledges the reply filed 1/12/2009 in which claims 1, 6, 12-13, and 18 were amended and new claims 25-27 were added. Currently claims 1-27 are pending for examination in this application.

### ***Claim Objections***

Claims 26 and 27 are objected to because of the following informalities:  
Regarding claims 26 and 27, each claim contains a grammatical error, "...the connection assembly according to any of claim 3, wherein...". Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 11-12, 15-16, and 24-27 rejected under 35 U.S.C. 102(b) as being anticipated by Thanawalla (USPN4,161,949). Thanawalla discloses an aseptic connector.

Regarding claims 1-6, 11-12, 15-16, and 24-27, Thanawalla discloses a connection assembly (Figure 3) capable transferring a fluid, particularly a fluid containing active products, from a reservoir to a medical delivery device comprising: a first connection element (12) capable of being associated with the reservoir and

comprising a first retaining means (64) and a reservoir interface (18); a second connection element (14) capable of being associated with the medical delivery device and comprising a medical delivery interface (28) and second retaining means (46) capable of cooperating with the first retaining means to form an irreversible connection between the two elements (Figure 5); at least one of the first and second connection elements comprises a perforator (70), which is capable of being reversibly connectable to standard connectors allowing fluid transfer therethrough before an irreversible connection is made with the other element (12), the respective retaining means (46) is positioned between the perforator (70) and the respective interface (28); and wherein the first and second retaining means are arranged such that they cooperate with each other by clipping during a single translation movement of one connection element with respect to the other to make the connection irreversible (Figures 3-5); wherein either the first or second retaining means comprises at least one elastically deformable tab (46) and the other retaining means comprises at least one lip (64) capable of cooperating with the tab (46); and wherein either the first or second connection element (12, 14) comprises a male part (30) and the other connection element comprises a female part (22) with a shape complementary to the male part and capable of cooperating with the male part so as to make the connection leak tight (Figure 5).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 18 is rejected under 35 U.S.C 103(a) as being unpatentable over Thanawalla (USPN4,161,949).

Thanawalla discloses a method for forming a connection for transferring a fluid (see abstract), comprising the steps of: translating the first connection element (12) having a first retaining means (64) and a reservoir interface (18) relative to the second connection element (14) having a second retaining means (40) and a medical delivery device interface (28), the respective retaining means is positioned between the perforator (70) and the respective interface; irreversibly connecting together the translated first and second connection elements (12, 14) through cooperation of the first and second retaining means (64, 40); and transferring a fluid between the first and second connection elements (Figures 3-5).

Thanawalla meets the claim limitations as described above except for the steps of connecting the connector to a reservoir. Lacking specific criticality, it would have been an obvious to connect the aseptic connector of Thanawalla to a reservoir for

delivery of a fluid since it is well known to use connector to connect tubing for delivery of fluids to a patient (col 1,ln 10-50).

***Claim Rejections - 35 USC § 103***

Claims 9 and 17 are rejected under 35 U.S.C 103(a) as being unpatentable over Thanawalla (USPN4,161,949) in view of Erskine et al. (USPN5,820,614). Thanawalla meets the claim limitations as described above except for the non-return means.

However, Erskine et al. teaches a connection for medical access devices.

Regarding claims 9 and 17, Erskine et al. teaches medical access connector (20, 30) for connection between a reservoir (14) and a delivery member (40) (Figures 2-2a) with an internal non-return means (52, 57) which prevents fluid return through the connector.

At the time of the invention, it would have been obvious to add the valve flow control means to the system of Thanawalla in order to prevent backflow through the assembly or provide for single unidirectional flow through the assembly. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Erskine et al. (cols 1-2).

***Claim Rejections - 35 USC § 103***

Claims 10, 13-14, and 19-23 are rejected under 35 U.S.C 103(a) as being unpatentable over Thanawalla (USPN4,161,949) in view of Folden (USPN5,221,267). Thanawalla meets the claim limitations as described above except for the weakened area that can be broken by shear force.

However, Folden teaches a breakable tubing coupling.

Regarding claims 10, 13-14, and 19-23, Folden teaches a connection device between a reservoir (29) and medical device (22, 24) that comprises a weakened area comprising a continuous notch (38) located behind an annular ring (50) that is breakable in response to shear force (Figure 3).

At the time of the invention, it would have been obvious to add the weakened section of Folden to the device of Thanawalla in order to allow for a quick disconnect of the connection without a knife or scissors. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Folden (cols 3-4).

#### ***Claim Rejections - 35 USC § 103***

Claim 7 is rejected under 35 U.S.C 103(a) as being unpatentable over Thanawalla (USPN4,214,586).

Regarding claim 7, Thanawalla discloses the claimed invention except for the specific connection tube taper.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Thanawalla with the taper connection tube as claimed since it well known to vary the size and shape of tubing connector depending on the fluid and area of the body to be treated, and since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

***Response to Arguments***

Applicant's arguments with respect to claims 1-27 have been considered but are moot in view of the new ground(s) of rejection.

***Suggested Subject Matter***

The following claim subject matter is suggested by the examiner and considered to distinguish patentably over the art of record in this application and is therefore presented to Applicant for consideration:

The Examiner suggests further clarification of the connection assembly drawn further clarification of the both perforators and the specifics of the clip arrangement as shown in Applicant's Figures 2b-2c.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 5:30am to 2:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date: 4/7/2009

/Christopher D Koharski/  
Examiner, Art Unit 3763

/Nicholas D Lucchesi/  
Supervisory Patent Examiner, Art Unit 3763